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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,384	11/14/2000	Murthy V. Simhambhatla	25141-0590	3452

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EXAMINER

RAGONESE, ANDREA M

ART UNIT	PAPER NUMBER
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3749

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/713,384

Applicant(s)

SIMHAMBHATLA ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 17-20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of **claims 9-16 and 21** in Paper No. 5 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 9-12, 15-16 and 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al. (US 5,759,172). Regarding **claim 9**, Weber et al. discloses a balloon catheter comprising a soft polymer blended and crosslinked with a multifunctional agent, so that the balloon **14, 41** exhibits compliant radial expansion to a desired working diameter within a first pressure range, and substantially less expansion about the first pressure range (column 4, lines 27-46). Regarding **claims 10-12 and 15-16**, Weber et al. discloses a balloon catheter comprising:

- longitudinally extending stiffening zones—as defined by the combination of stiff sections **16, 44** and pliable sections **15, 45**—circumferentially disposed on at least a section of the balloon **14, 41**, which expand with adjacent portions of balloon **14, 41** such that the balloon section expands to a substantially cylindrical configuration (column 3, lines 1-5);

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- wherein the longitudinally extending stiffening zones **16/15, 44/45** comprise a polymeric material coextruded as an intermittent first layer of balloon **14, 41** (column 3, lines 66-67 and column 4, lines 1-18);
- wherein the longitudinally extending stiffening zones **16/15, 44/45** comprise cross-linked polymeric material (column 4, lines 27-46);
- wherein the longitudinally extending stiffening zones **16/15, 44/45** are symmetrically spaced and configured to control axial growth of balloon **14, 41** during inflation thereof, as shown in Figure 3; and
- wherein the stiffening zones **16/15, 44/45** define in part an outer most edge of expanded balloon **14, 41**, as shown in Figure 3, where stiffening section **16** form channels **20** while pliable sections **15** expand into lobes **21** (column 6-13).

Regarding **claim 21**, Weber et al. discloses a balloon catheter comprising a balloon **14, 41** having a coating of crosslinked circumferentially spaced longitudinal zones **16/15, 44/45** configured to control axial growth (column 3, lines 1-5 and column 4, lines 27-46).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 13-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. (US 5,759,172) in view of Chen et al. (US 5,565,523). Weber et al. teaches a balloon catheter apparatus comprising all limitations recited in **claims 13-14**,

with the exception of at least one specific polymer with glass transition temperature of about 20° C to about 60° C selected from the group consisting of polyamide-ether block copolymer, polyether-ester block copolymer, polyester-ester block copolymer, polyester-urethane block copolymer, polyether-urethane block copolymer, polycarbonate-urethane block copolymer, polyolefin, and polyolefin block copolymer. Chen et al. teaches the use of at least one of these polymers for use in making medical devices including catheters and balloons for dilatation catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the specific polymers as the material used to make the balloon catheter of Weber et al. because, as taught by Chen et al., it is well-known in the art to utilize these such polymers since they exhibit a relatively low flexural or tensile modulus, a relatively high tensile strength and a relatively high elongation to break—material characteristics that are generally desirable in medical devices—in order to provide for controlled axial or radial expansion (column 4, lines 19-54).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Saltman (US 4,871,810), Saltman (US 5,091,478), Baigrie et al. (US 5,250,228), Chu et al. (US 5,317,061) and Baigrie et al. (US 5,382,384) all disclose polymer compositions.

Walinsky (US 5,108,370), Davey (US 5,318,587), Campbell et al. (US 5,456,666), Campbell et al. (US 5,458,572), Campbell et al. (US 5,478,319), Inderbitzen

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et al. (US 5,484,411), Janacek (US 6,129,706) and Fagan et al. (WO 95/17223) all disclose balloon catheter apparatuses.

Chen et al. (US 5,554,120), Chen et al. (US 5,747,591), Hamilton et al. (US 5,797,877), Chen et al. (US 5,849,846), Chen et al. (US 6,013,728), Rau et al. (US 6,024,722), Hamilton et al. (US 6,086,556), Simhambhatla et al. (US 6,270,522 B1), Ferrari et al. (US 6,190,357 B1), Simhambhatla et al. (US 6,336,936 B2), Simhambhatla et al. (US 6,428,506 B1), Simhambhatla et al. (US 2001/0027329 A1) and Chen et al. (US 2002/0077418 A1) all disclose polymeric material used in making medical devices.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **(703) 306-4055**. The examiner can normally be reached on Monday through Thursday from 6:30 am until 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on (703) 308-1935. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.


Ira S. Lazarus
Supervisory Patent Examiner
Group 3700

amr
September 6, 2002